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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,191	12/31/2001	Semyon Shchervinsky	ETH-1603	7167
7590 05/28/2004			EXAMINER	
Selitto, Behr & Kim 203 Main Street Metuchen, NJ 08840			SCHAETZLE, KENNEDY	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/039,191

Applicant(s)

SHCHERVINSKY, SEMYON

Examiner

Kennedy Schaetzle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13-17 and 20-24 is/are rejected.
- 7) ☒ Claim(s) 10-12, 18 and 19 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5-31-02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Mayer et al. (Pat. No. 4,827,940).

Claims 1 and 2 are clearly anticipated.

3. Claims 1, 4, 5, 6, 13, 14, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Bush et al. (Pat. No. 5,683,447).

Regarding the use of a bioabsorbable coating, see col. 7, lines 3-5.

Regarding claim 4, see Fig. 6.

Regarding claims 6 and 14, Fig. 6 shows electrode 22 to be composed of wire with a circular cross-section.

Regarding claims 21 and 22, Fig. 6 shows a bare electrode wire (pacing wire 45) with a distal tip formed into a harpoon-like shape (i.e., a single barb) to establish a conductive anchor. The paragraph abridging columns 6 and 7 discloses the teaching to shield the fixation barb by using a bioabsorbable material.

4. Claims 13 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaldach (Pat. No. 5,922,015).

Concerning claim 13, the examiner considers each element 14 (see Fig. 6b) to constitute an anchor with a harpoon-like shape with a single barb.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al. (Pat. No. 4,827,940).

Although Mayer et al. do not explicitly refer to a coating of glycosides; a L-lactide; a D-lactide, etc., the courts have long established that the selection of a known material based on its suitability for its intended use is obvious (*Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945)). Clearly the selection any known biocompatible, bioabsorbable material would have been considered obvious by those of ordinary skill in the electrode arts. The applicant gives no criticality in any one specific material over the other, and it would appear that the coatings used by Mayer et al. would work equally as well.

7. Claims 7-9, 15-17, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bush et al. (Pat. No. 5,683,447).

With regards to claim 7, while Bush et al. teach that the pacing hook 28 may have various cross-sectional geometries including circular and rectangular (col. 5, lines 19-27), no discussion as to the nature of the alternate embodiment barb shape is given. Bush et al., however, teach that such a flattened shape allows for flexibility in the lead axis direction, while enabling the hook to be stiff in the transverse direction to reduce the potential for tissue damage upon implant (col. 6, lines 1-6). Those of ordinary skill in the art recognizing the interchangeability of the hook, helix and barb mechanisms, would have seen the obviousness of incorporating a distal flattened barb section of the wire 45 in order to take advantage of this property. A similar comment applies to claim 15.

Regarding claims 8 and 16, the examiner considers a flattened barb to be obvious as reasoned above. Such a barb necessarily includes a pair of flat, planar surfaces lying on opposite sides of a plane containing the central longitudinal axis of the wire 45—one planar surface being represented by that section of the barb that extends directly along the axis of the wire and facing away from lumen 39, and the other planar surface being represented by that section of the flattened barb that is shown in Fig. 6 as lying closest to lumen 39.

The limitation set forth in claims 9 and 17 is clearly shown in Fig. 6.

Concerning claim 23, note the reasoning used in the rejection of claims 7 and 15 above.

Regarding claim 24, note col. 7, lines 3-5.

Allowable Subject Matter

8. Claims 10-12, 18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record does not appear to contain a teaching for incorporating a surgical electrode with a single asymmetrical barb made from a flattened section of multistrand wire. The applicant in the first paragraph of page 11 gives criticality to this feature.

In reference to claim 12, the prior art fails to disclose a temporary cardiac pacing wire comprising an anchor coated with a bioabsorbable material. Prior art temporary cardiac pacing wires are cited that comprise anchors wholly made out of bioabsorbable material, but do not teach to coat the anchor. Any suggestion to coat the prior art anchors would effectively destroy the references.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

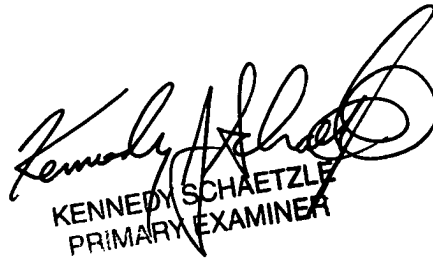
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
May 26, 2004



KENNEDY SCHAEETZLE
PRIMARY EXAMINER